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10/540,108	06/26/2006	Bo Rud Nielsen	P70653US0	1450

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EXAMINER	
HEYER, DENNIS	

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,108	NIELSEN ET AL.	
	Examiner	Art Unit	
	DENNIS HEYER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/02/2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of Applicant's remarks and amendments filed September 2, 2008. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 11 – 21 are currently pending

Withdrawn Rejections

Claim rejections – 35 USC § 112 – 2nd Paragraph

The rejection of Claims 11 – 17 and 21 under 35 U.S.C 112 2nd paragraph as being indefinite and failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention is withdrawn in response to Applicant's amendment.

New and/or Maintained Rejections

Maintained Rejections

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen in US 2002/0037943 (published: March 28, 2002) in view of Hunter *et al.* in US 2004/0043052 (filed: May 27, 2003).

With respect to claims 11, 17, 19 and 20, Madsen discloses in Examples 2 and 3, a method for the preparation of a cross-linked hydrophilic coating of a hydrophilic polymer on a substrate polymer surface of a medical device (catheter), said method

comprising the steps of (i) providing a medical device comprising a substrate polymer having the substrate polymer surface, (ii) providing a polymer solution comprising 1-20% by weight of a hydrophilic polymer and 0-5% by weight of additive(s), (iii) applying said polymer solution to said substrate polymer surface, (iv) evaporating at least a part of the vehicle from said polymer solution present on said substrate polymer surface, and curing said hydrophilic polymer (Example 1).

Madsen further discloses providing a plasticizer [0070], however fails to expressly disclose the polymer solution comprises a vehicle with plasticizing effect on the hydrophilic polymer, said vehicle comprising at least one plasticizer having a solubility in water of at least 6 g/L, a boiling point above 210°C at 760 mmHg, and a Hansen δ_H parameter of less than 20. However, it is well known in the art to coat a catheter with a polymer utilizing triethyl citrate as the plasticizer, as taught by Hunter et al. [0095], [0109]. Since applicant's example includes the same plasticizer, examiner interprets the triethyl citrate has the same properties as claimed. It would have been obvious to one of ordinary skill in the art to modify the type of plasticizer used in order to attain a coating with the desired properties (desired flexibility). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

With respect to claim 12, the modified Madsen discloses the polymer solution is applied to said substrate polymer surface in one single application step (dipping) (Examples 2 and 3)

With respect to claim 13, the modified Madsen discloses the vehicle comprises at least one solvent (ethanol) (Examples 2 and 3).

With respect to claim 14, the modified Madsen discloses the polymer solution has the ranges claimed, with the exception of the content range of plasticizer. However, it would have been obvious to one of ordinary skill in the art to modify the desired range of the plasticizer depending on the desired properties (e.g. amount of flexibility of the coating). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With respect to claim 15, the modified Madsen discloses the substrate polymer is polyurethane (Example 2).

With respect to claims 16 and 21, the modified Madsen discloses the hydrophilic polymer is polyvinyl pyrrolidone (Examples 2 and 3).

With respect to claim 18, Madsen discloses a medical device comprising a hydrophilic coating of a cross-linked hydrophilic polymer, wherein the coating comprises a hydrophilic plasticizer ([0070], Examples 2 and 3). Madsen fails to expressly disclose the plasticizer has a solubility in water of at least 6 g/L, a boiling point above 210°C at 760 mmHg, and a Hansen δ_H parameter of less than 20. However, it is well known in the art to coat a catheter with a polymer utilizing triethyl citrate as the plasticizer, as taught by Hunter et al. [0095], [0109]. Since applicant's example includes the same plasticizer, examiner interprets the triethyl citrate has the same properties as claimed. It would have been obvious to one of ordinary skill in the art to modify the type of

plasticizer used in order to attain a coating with the desired properties (desired flexibility). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

Applicant's arguments filed September 2, 2008 with respect to the rejection under 35 U.S.C 103(a) of Claims 11 – 21 as being unpatentable over Madsen in US 2002/0037943 in view of Hunter *et al.* in US 2004/0043052 have been fully considered but are not found to be persuasive.

With respect to the Madsen reference, Applicant contends that the instantly claimed method (instant Claim 1) is distinguished from that taught by Madsen because Madsen teaches that plasticizers may be part of a wetting liquid (paragraphs [0067] – [0071]) and not as part of the polymer solution used for coating the catheter with the hydrophilic polymer, as recited in Applicant's invention. Applicant further notes that Madsen teaches that the catheter is stored in the sterile wetting solution, in a sealed package for use (paragraphs [0093 – [0107]). Applicant argues that the wetting solution taught by Madsen contains plasticizers that do not result in coatings having sufficient integrity or bonding strength for Applicant's intended purpose.

In response, the Examiner will first comment on Applicant's arguments that the Madsen method of coating may be distinguished from that of Applicant. Madsen teaches a step in which a wetting solution comprising a polymer (PVP) and a plasticizer

is applied to the catheter substrate. This “wetting” process is followed by irradiation of the coated catheter (i.e. sterilization by irradiation, see page 4, paragraphs [0070] and Example 1 paragraph [0095]). The irradiation step may reasonably be interpreted as being equivalent to “curing". Further, the fact that irradiation occurs while the substrate is “wetted" may reasonably be interpreted as equivalent to instant Claim 1, step iv, of Applicant’s invention: “evaporating at least a part of the vehicle from said polymer solution present on said substrate polymer surface and curing said hydrophilic polymer". The fact that Madsen teaches that a substrate surface is ‘wetted’ means nothing more than ‘the substrate is not completely dry’ prior to curing. In both the Madsen and Applicant’s methods there is no requirement that all of the polymer solution be evaporated prior to curing. The fact that the Madsen method comprises additional steps (such as the crosslinking step prior to application of the wetting solution does not exclude said method from reading on that of Applicant which also employs the open language 'comprising'.

The Examiner will now comment on Applicant’s contention that Madsen teaches that the “catheter is stored in the sterile wetting solution, in a sealed package for use” (paragraph [0093] - [0107]). A careful reading of the cited paragraphs fails to reveal such a teaching. Thus it is reasonable that the term “wetted’ does not require immersion of the catheter substrate in a sealed package of wetting solution with no possibility for evaporation of at least a portion of the polymer solution.

Finally, the Examiner will address Applicant's argument that the Madsen reference teaches plasticizers that do not result in coatings having sufficient integrity or

bonding strength for Applicant's intended purpose. In response it is noted that this represents an argument against a reference individually and one cannot show nonobviousness by attacking references individually (Madsen) where the rejections are based on a combination of references (Madsen plus Hunter). See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With respect to the Hunter reference, in summary, Applicant argues that the Hunter reference is not generally directed to hydrophilic coatings of medical devices but, instead, coatings that contain therapeutic agents on the surface of coated devices. Applicant notes that the portion of Hunter cited by the Examiner is, in fact, directed to medical devices and to the polymer coatings having plasticizers such as glycerol and triethyl citrate. Applicant points out that glycerol is not an acceptable plasticizer and thus teaches away from their claimed method. Applicant further argues that a more detailed reading of the Hunter reference reveals that the polymer coatings taught by Hunter are not intended to increase lubricity and thus reduce friction of a device, as disclosed and claimed in the instant Application, but for their ability to form hydrogen or ionic bonds with the therapeutic agents. Accordingly, Applicant argues the Hunter reference provides no motivation by one of ordinary skill in the art to choose the plasticizer's instantly claimed to improve the lubricious properties of polymer coatings.

In response to applicant's argument that the Hunter reference is not directed toward plasticizers that increase lubricity and reduce friction of polymer coatings, a recitation of the intended use of the claimed invention must result in a structural

difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Further in response to Applicant's statement above, relating to the intended use of plasticizers in the instant Application, it is noted that increased lubricity and reduced friction of a device, is disclosed but not claimed.

In the Hunter reference, the plasticizers glycerol and triethyl citrate are taught to increase the *flexibility* of the coating, specifically: "This polymer coating can further contain agents that can increase the flexibility (e.g., plasticizer -- glycerol, triethyl citrate).....of the coating" (Hunter et al., paragraph [0109]). The teaching of two potential plasticizers to increase flexibility hardly qualifies as a "general recitation of known prior art polymers and plasticizers" as Applicant contends. Further, the intended use of the Hunter plasticizers, to increase the flexibility of the coating, while different from that of Applicant's, would clearly be recognized by one of ordinary skill in the art as a desirable property of a medical device such as a catheter. Thus one of ordinary skill in the art, guided by the teachings of Hunter, would be motivated to try the two plasticizers disclosed with a reasonable expectation of improving the flexibility and the lubricity of the polymer coating.

In KSR v. Telefex, 82 USPQ2d 1385, 1397 (U.S. 2007), the Supreme Court has held that when there is market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person has good reason to pursue known options within his or her technical grasp. Under these conditions, "obviousness to try"

such options is permissible. In this instance, a market pressure exists in the medical/pharmaceutical industries to improve the coating properties of a medical device such as a catheter. Accordingly, it would have been obvious to have examined the available plasticizer options presented by Hunter et al. as they have been taught to improve the flexibility of said devices.

Conclusion

Claims 11 – 21 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615